

MINUTES
KENTUCKY BOARD OF PHARMACY
Spindletop Administration Building, Suite 302
2624 Research Park Dr.
Lexington, Kentucky

December 17, 2008

CALL TO ORDER: A regular meeting of the Kentucky Board of Pharmacy was held at the Board Office at Spindletop Administration Building, 2624 Research Park Drive, Lexington, Kentucky. President Leake called the meeting to order at 9:18 a.m.

Members present: Mike Leake, Peter Orzali, Anne Policastri, Sandy Simpson, Catherine Shely and Patricia Thornbury. Staff: Michael Bureson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Katie Busroe, Steve Hart and Phil Losch, Pharmacy and Drug Inspectors; Lisa Atha, Executive Secretary; Cheryl Lalonde, Assistant Attorney General and Board Counsel; and Brian Fingerson, Pharmacist Recovery Network Committee. Guests: Ralph Bouvette, and Sam Lyons, APSC; Brad Hall, Kentucky Pharmacists Association; Kim Morgan, Target; Scott Greenwell, Humana; Larry Hadley and Joel Thornbury, Board members-elect; Chris Killmeier, Walgreens; Brandi Johnson, CVS; Mike Wyant, Cardinal Health; Brandon Green, University of Kentucky College of Pharmacy; Kathleen Coffey; Maxine Snively; Sandy, Phoebe and Jade Thornbury; William Thornbury; Kathleen Coffey; Richard Ross; Greg Jacobs and Melissa Jacobs. Juanita Toole, Court Reporter, recorded the meeting.

MINUTES: On motion by Dr. Policastri, seconded by Mr. Orzali and passed unanimously, the Minutes of November 14, 2008 Board Meeting were approved as amended. On motion by Ms. Thornbury, seconded by Ms. Simpson and passed unanimously, the Minutes of November 15-16, 2008 Board Retreat were approved as amended.

APPEARANCE: **Diana Clarkson.** The appearance of Diana Clarkson was cancelled due to the Pharmacist Recovery Network Committee being cancelled due to bad weather.

INTERAGENCY:

Tramadol Regulation. 902 KAR 55:030 was amended to include tramadol as a Schedule IV controlled substance in Kentucky, effective December 5, 2008. The Board office worked with the Drug Enforcement and Professional Practices Branch of the Office of Inspector General to disseminate this information. Pharmacies have 30 days to comply with the amended regulation.

BOARD REPORTS:

Board President. President Leake stated that the Advisory Council met and will present recommendations regarding medication error regulation changes and an educational program for pharmacists at the January 14, 2009 Board Meeting.

Board Members. Ms. Thornbury. Ms. Thornbury stated that since the Board's representative on the Advanced Registered Nurse Practice Council has to be a Board Member, per KRS 314.193, she will resign as of December 31, 2008. The Board will appoint a new representative at the January 14, 2009 Board Meeting. Ms. Thornbury was appreciative for the interesting experience of serving on the Council.

Dr. Policastri. Dr. Policastri is on the 2009 NABP/AACP District III planning committee. Main topics for the meeting include the expanded roles of pharmacists, pharmacist technicians and increased use of technology. Correspondence will be sent to all District III states to determine each state's status regarding the action plans that were decided upon at the 2008 NABP/AACP District III meeting. There is some concern about attendance at the meeting due to state budget cuts.

Dr. Shely. Dr. Shely thanked the Board for allowing her to attend the ASHP Midyear Meeting. She attended a joint ASHP/NABP session for all ASHP members who are also members of NABP. The session had 3 main focuses: technician issues, including the lack of technician registration in all states and the inconsistency of technician training programs; multistate licensure in which NABP is very interested in partnering with state boards of pharmacy to act as a clearing house for pharmacists in the event of a disaster, not to allow pharmacists to move from state to state at any time; and accreditation of community pharmacies for which NABP is currently soliciting comments.

Board Executive Director. 1) EMars monthly report for November 2008 was presented to the Board. 2) An Advanced Registered Nurse Practice Council representative will be elected at the January 14, 2009 Board Meeting. 3) The compounding regulation and the amended central refill regulation were filed. 4) The wholesaler regulation was filed with the statements of consideration. 5) Mr. Burleson attended the NABP Symposium that focused on counterfeiting in drug wholesalers and internet pharmacies.

Board Staff. Phil Losch. Mr. Losch thanked the Board for allowing him to go the ASHP Midyear Meeting.

Jeff Osman. Dr. Osman thanked the Board for the years of support in his position.

PRN Committee. Brian Fingerson thanked Greg Jacobs for his years of service on the PRN Committee. CAPTASA will be held January 23 and 24, 2009 in Lexington.

CURRENT/PENDING CASES:

Case Updates: Dr. PolICASTRI moved for acceptance and entry of the proposed Agreed Orders as written. Mr. Orzali seconded, and the motion passed with Ms. Thornbury abstaining.

Case No. 05-0015; Case No. 08-0073B; Case No. 08-0094; Case No. 08-0096; Case No. 08-0097A; Case No. 08-0097B; Case No. 08-0099; and Case No. 08-0102.

Case Review: Mr. Orzali moved for acceptance of the Case Review Committee recommendations for the following case reports. Dr. Shely seconded, and the motion passed with Ms. Thornbury abstaining.

Case No. 08-0077A. REVISIT. Pharmacy permit holder allegedly sold a misbranded product by giving the patient a partially filled prescription, then shipping remainder to patient at the address on file. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0077B. REVISIT. Pharmacist allegedly sold a misbranded product by giving the patient a partially filled prescription, then shipping remainder to patient at the address on file. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0078. REVISIT. Pharmacist allegedly engaged in unprofessional or unethical conduct pertaining to a patient's privacy by discussing the complainant's pharmacy care. Alleged violation of law: KRS 315.121(2)(b). CRC Recommendation: Case is dismissed.

Case No. 08-0109A. Pharmacy permit holder allegedly dispensed 66 sotalol 80mg tablets when the correct quantity should have been 180 and the prescription was labeled as 180 tablets. Alleged violation of law: KRS 217.065(1). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0109B. Pharmacist allegedly dispensed 66 sotalol 80mg tablets when the correct quantity should have been 180 and the prescription was labeled as 180 tablets. It is also alleged that this pharmacist may have inappropriately transferred 2 other prescriptions for a patient by giving the wrong prescriber. Alleged violation of law: KRS 217.065(1). CRC Recommendation: There is sufficient evidence of a violation; however, the penalty shall be the issuance of a Letter of Reprimand.

Case No. 08-0109C. Pharmacy permit holder allegedly dispensed Lotemaz eye drops with incomplete dosing directions. Alleged violation of law: KRS 217.065(6). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0109D. Pharmacist allegedly inappropriately dispensed Lotemaz eye drops with incomplete dosing directions. Alleged violation of law: KRS 217.065(6). CRC Recommendation: There is sufficient evidence of a violation; however, the penalty shall be the issuance of a Letter of Reprimand.

Case No. 08-0109E. Pharmacy permit holder allegedly dispensed two prescriptions with the wrong prescriber recorded on the label. It was assumed by the complainant that the transferring pharmacy had inappropriately given the name of the wrong prescriber to this pharmacy. Alleged violation of law: 201 KAR 2:165. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0109F. Pharmacist allegedly dispensed two prescriptions with the wrong prescriber recorded on the label. It was assumed by the complainant that the transferring pharmacy had inappropriately given the name of the wrong prescriber to this pharmacy. Alleged violation of law: 201 KAR 2:165. CRC Recommendation: There is sufficient evidence of a violation; however, the penalty shall be the issuance of a Letter of Reprimand.

Case No. 08-0110A. Pharmacy permit holder allegedly engaged in unprofessional and unethical conduct by committing a medication error and by releasing patient information to an unauthorized person. Alleged violations of law: KRS 315.121(1)(a) and (2)(b) and (e). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0110B. Pharmacist allegedly engaged in unprofessional and unethical conduct by committing a medication error and by releasing patient information to an unauthorized person. Alleged violations of law: KRS 315.121(1)(a) and (2)(b) and (e). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0112. Pharmacist allegedly failed to obtain the required 1.5 continuing education units for 2007. Alleged violations of law: KRS 315.065 and 201 KAR 2:015 Section 5(1)(a). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0113A. Pharmacy permit holder allegedly closed without proper notification to the Board Office. Alleged violations of law: 201 KAR 2:106 Section 2 and 201 KAR 2:205(3)(e). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director

is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0113B. Pharmacist-in-charge allegedly closed without proper notification to the Board Office. Alleged violations of law: 201 KAR 2:106 Section 2 and 201 KAR 2:205(3)(e). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0114. Manufacturer allegedly failed to properly label finished product containers with the name and address of manufacturer. Alleged violation of law: KRS 217.065. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0115A. Pharmacy permit holder allegedly had misbranded drugs in the pharmacy during a FDA audit. Alleged violations of law: KRS 217.065 and KRS 315.121(1)(a) and 2(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0115B. Pharmacist allegedly pled guilty to a misdemeanor in federal court regarding the misbranding of drugs found in the pharmacy during a FDA audit. Alleged violations of law: KRS 217.065 and KRS 315.121(1)(a) and 2(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0116. Pharmacist allegedly violated a previous Agreed Order by practicing at a pharmacy without receiving permission from the Board. Alleged violation of law: KRS 315.121(1)(i). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0117A. Pharmacy permit holder allegedly failed to produce a hard-copy daily computer printout of all original and refill prescription data. Alleged violations of law: 201 KAR 2:170 and 201 KAR 2:205. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0117B. Pharmacist-in-charge allegedly failed to produce a hard-copy daily computer printout of all original and refill prescription data. Alleged violations of law: 201 KAR 2:170 and 201 KAR 2:205. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0118. Pharmacist allegedly failed to complete fifteen hours of CE in 2006 for his 2007 pharmacist's license renewal. Alleged violations of law: KRS 315.065 and 201 KAR 2:105. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

RECIPROCITY/RELICENSURE/INTERNSHIP:

Kavita Parikh. Ms. Parikh requested reinstatement of her Kentucky pharmacist's license which had lapsed in 1999. She has not practice pharmacy in any state since May 1999. After discussion, Mr. Orzali moved to allow reinstatement of Kavita Parikh's Kentucky pharmacist's license upon successful completion of the NAPLEX and MPJE and completion of 500 hours of internship approved by the Executive Director. Ms. Thornbury seconded, and the motion passed unanimously.

CORRESPONDENCE/COMMUNICATIONS:

UPS Supply Chain Solutions. UPS Supply Chain Solutions requested an alternative to printing a hard copy of each day's pharmacy transactions by storing the records electronically with the ability to print hard copies if requested. Ms. Thornbury moved to allow UPS Supply Chain Solutions to use an alternative electronic system of data storage and daily log. Ms. Simpson seconded, and the motion passed unanimously.

ExcelleRx. ExcelleRx requested a waiver of the pharmacist-in-charge being present for a minimum of 10 hours per week. ExcelleRx is licensed as an out of state pharmacy providing Hospice care in Kentucky per KRS 315.295. After much discussion, Dr. Shely moved for the Executive Director to communicate to ExcelleRx that a waiver is not necessary per KRS 315.0351, but that the Board reserves the right to inspect and insure

compliance with KRS 315.295 and 201 KAR 2:260. Ms. Thornbury seconded, and the motion passed unanimously.

Suncare Medical. Tom Gravely, pharmacist-in-charge for Suncare Medical, requested a waiver of the pharmacist-in-charge being present for a minimum of 10 hours per week. Dr. Shely moved to deny the request that the pharmacist-in-charge of Suncare Medical be present in the pharmacy less than 10 hours per week. Mr. Orzali seconded, and the motion passed unanimously.

LEGISLATION/REGULATIONS.

201 KAR 2:050, Licenses and permits; fees. 201 KAR 2:050 would be amended to separate the fees associated with manufacturers and wholesale distributors. Dr. Shely moved to accept 201 KAR 2:050 as presented and file by January 15, 2009, with a hearing date of February 23, 2009 at 9:00 am at the Board office. Dr. Policastri seconded, and the motion passed unanimously.

CONTINUING EDUCATION:

Dr. Shely moved to accept the continuing education programs 08-62 and 09-01 through 09-03 as recommended. Ms. Thornbury seconded, and the motion passed unanimously.

OLD BUSINESS: Dr. Osman presented a proposal of allowing continuing education credit for Board Meetings. Ms. Thornbury moved that continuing education credit would be allowed for Board Meetings with parameters, Dr. Policastri seconded and the motion then passed unanimously.

NEW BUSINESS: President Leake called for nominations for 2009 President Elect. Mr. Orzali nominated Dr. Policastri. Ms. Thornbury seconded the nomination and the motion passed unanimously. Ms. Thornbury moved that the nomination of Dr. Policastri for President Elect 2009 be accepted by acclamation. Ms. Simpson seconded, and Dr. Policastri was elected by acclamation.

Dr. Osman swore in Joel Thornbury and Larry Hadley as new Board Members for Jan 2, 2009- Jan. 1, 2013.

ADJOURNMENT: On motion by Ms. Thornbury, seconded by Dr. Policastri and passed unanimously, President Leake adjourned the meeting at 12:30 p.m. The next regularly scheduled Board Meeting is scheduled to begin at 9:00 a.m. on January 14, 2009 at Board Office in Lexington, Kentucky.

Michael Burleson, R.Ph.
Executive Director

